Important
User Notice

Check Applicators and Transfer Tubes aging, integrity and suitability

Product: microSelectron and Flexitron

Date: 17 January 2014
FCO: IUN 799701-01

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Important User Notice

We are providing the information in this FCO to notify you of a possible safety issue that may exist on your equipment and to inform you of action you can take to safeguard both your staff and your patients. We ask that you please read and understand the content of this notice and recommend implementation of the measures provided.
We also need you to acknowledge this FCO by signing and returning the statement on the FCO Action Notification Report.
We advise you to insert this Notice in the applicable copy of the User Manual.

Check Applicators and Transfer Tubes aging, integrity and suitability

Product: microSelectron and Flexitron

Date: 17 January 2014
FCO: IUN 799701-01

Scope:	All users of microSelectron and Flexitron
Problem:	Unintended disconnection of the transfer tube and/or applicator and possible failure to retract the source cable from the transfer tube, caused by: • The use of damaged applicators or transfer tubes • The use of kinked or contaminated transfer tubes • The use of parts beyond their technical lifetime • The use of unsuitable transfer tubes
Clinical impact:	Possible inadvertent irradiation of patient and hospital staff
Solution:	To take every precaution to prevent the Problem described from occurring, these are steps that can be taken. Make sure to inspect transfer tubes, applicators and accessories on a regular basis and always prior to each use, according to the instructions in the applicable user manual. If a part has unacceptable wear or damage, of the kind described in the user manual, then it is recommended to remove it from clinical use. Please pay attention to the specified life expectancy of applicators and transfer tubes, which are the limits to which the components were tested. Elekta recommends to only use applicators, accessories and transfer tubes that are within their specified life expectancy and to replace any applicators, accessories and transfer tubes that are beyond the specified life expectancy as stated in the user manual. GYN Transfer tubes produced before 2007 have known deficiencies (and are past their life expectancy), should be removed them from clinical use. Finally, please make sure to only use transfer tubes specified for your specific afterloader and applicator.
Technical Reference:	CLM 1643523; CLM 1658652; CLM 1569261; FPR 325929 These are actual complaint cases registered by Elekta, in which incorrect or worn applicators and/or transfer tubes were the cause of issues, such as described under the Problem header, above.
Contact:	If you have any queries about this Notice, please contact your local Elekta office.

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1 Safety reference

The recommendations in this user notice fall under the process of checking your applicators and transfer tubes regularly and always prior to use regarding aging, integrity and suitability. As part of this process, Elekta recommends to remove parts from clinical use that have unacceptable wear or damage to them, as revealed by your inspection.

2 Scope

This Important User Notice is applicable to all users of microSelectron and Flexitron afterloaders, specifically relating to the use of applicators, accessories and transfer tubes.

Additionally Gynecological Transfer Tubes with the following part numbers, produced before 2007 (revision 00, 01 and 02) should be removed from clinical use and properly disposed of, as they have known deficiencies and are also outside their expected life window:

- GYN Transfer Tube keyed for Channel 1: 111002 (revision 00, 01, 02)
- GYN Transfer Tube keyed for Channel 2: 111003 (revision 00, 01, 02)
- GYN Transfer Tube keyed for Channel 3: 111004 (revision 00, 01, 02)

3 Related Documents

Reference	Revision	Description
NA		

4 Problem Description

During the past months, Elekta has experienced an increasing number of incidents related to the use of old, damaged or unsuitable applicators and transfer tubes with microSelectron and Flexitron afterloaders.

The User Manuals for all specific parts contain clear guidelines on life expectancy, cleaning, inspection and suitability. The increase in incidents has given rise to the assumption that this information is not always known and, therefore, instructions are not always followed as intended. It is Elekta's responsibility as a medical device manufacturer to bring such information to the clinical user's attention, if safety-related problems could occur as a consequence of the information being unknown.

This Important User Notice is a reminder of the recommended process for checking your Applicators and Transfer Tubes regularly and always prior to use regarding aging, integrity, cleanness and suitability and to remove parts with unacceptable wear or damage from clinical use and dispose of them properly.

Next to these checking procedures for all applicators and transfer tubes, another reminder is included in this Important User Notice, regarding certain types of gynecological transfer tubes, as referenced above. Transfer tube connectors have a mechanism to ensure that the check cable or source cable cannot pass through the connector in case an applicator is correctly connected. In the referenced Gynecological Transfer Tubes that were produced before 2007, this mechanism comprises of two steel ball-bearings. In

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case such a transfer tube becomes disconnected from the applicator while the source or check cable is inside the applicator, the capsule may become stuck in the space between the two ball-bearings, upon retraction of the cable.

5 Consequences

Unintended disconnection of the transfer tube and applicator and possible failure to automatically retract the source cable from the transfer tube caused by:

- The use of damaged applicators or transfer tubes
- The use of kinked or contaminated transfer tubes
- The use of applicators and transfer tubes beyond its technical lifetime
- The use of unsuitable transfer tubes

Such an unintended disconnection will most likely result in an interruption of treatment and a disruption of the workflow. In a worst-case scenario, inadvertent irradiation of patients or staff could result.

6 Resolution

To minimize the probability of the Consequences described in the previous paragraph from occurring, these are the steps that can be taken.

Please check your applicators and transfer tubes regularly and always prior to use regarding aging, integrity, cleanness and suitability. The following parts should be removed from clinical use:

- The referenced GYN Transfer tubes, produced before 2007, since they have known deficiencies;
- Transfer tubes, applicators and that have unacceptable wear and damage to them;
- Transfer tubes that were not intended for your specific afterloader and applicator.

Applicators, accessories and transfer tubes that are beyond their specified life expectancy, as specified in the user manual, are recommended for frequent inspection and replacement consideration.

6.1 Life expectancy

This section further clarifies the life expectancy of applicators and transfer tubes.

All medical devices are subject to a stringent set of regulations, most of them related to patient and staff safety. As part of these regulations, all claims that a manufacturer makes about products must be supported by filed test evidence. For applicators, the category of tests that leads most directly to the life expectancy is the number of sterilization cycles. For transfer tubes, multiple parameters apply, among which repeated connection/disconnection tests and tests that verify the stability of the length of the transfer tube over time.

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An example of test evidence, for one of the applicators, is included in the appendix. Based on this evidence Elekta can claim the following life expectancy figures for different products:

- Resterilizable applicators and accessories have a 3 year life expectancy, based on 300 sterilization cycles;
- microSelectron Transfer Tubes have a 2 year life expectancy;
- Flexitron Transfer Tubes have a 3 year life expectancy;
- For all other accessories, please refer to the applicable user manual for the life expectancy.

Applicators, transfer tubes and accessories that are beyond the life expectancy are recommended for frequent inspection and replacement consideration. Elekta cannot assume liability for these products if used past their life expectancy.

6.2 GYN Transfer Tubes, produced before 2007

Gynecological Transfer Tubes with the above listed parts numbers (111002, 111003, 111004) and revisions (00, 01, 02) should be removed from clinical use.

You can check the revision number which is engraved on the indexer connector of the transfer tube and compare it to the numbers given. A visual way to determine if this is one of the affected transfer tubes is to check the number of ball-bearings inside the transfer tube connector:

Gynecological Transfer Tubes that have connectors with two ball-bearings should be removed from clinical use.

6.3 Regular inspections

It is the responsibility of the user to inspect transfer tubes, applicators and accessories on a regular basis and always prior to each use, according to the instructions in the applicable User Manual. Parts that exhibit unacceptable wear or damage are recommended to be removed from clinical use.

Applicable inspections for applicators & accessories, before use:

- Inspect applicators for any indication of unacceptable deterioration, dullness, cracking, staining, corrosion, discoloration or bending. Inspect joints and connections on play, strength or other forms of degradation. Do not attempt to repair the product.

Transfer Tubes inspections before use:

- All parts to be used must be clean;
- Visually inspect parts for indication of kinking, weakening, bending, corrosion, discoloration or general deterioration;
- Check that no other obstructions are present;
- Check the secure connection with the suitable applicator.

Transfer Tubes regular inspections:

- Check the reference length by performing a source position check or measure the length with a tape-measure;
- Check that the source positioning accuracy is within specification.

To prevent damage of the transfer tubes do not apply excessive forces to the transfer tube. Excessive force can change the length of a transfer tube. To prevent kinking, ensure that the transfer tubes are not bent tightly.

6.4 Check suitability

Different Transfer Tube Sets are suitable for the different type of afterloaders and should never be used on a different afterloader then specified, in the User Manual:

- microSelectron Classic
- microSelectron V2 and Digital
- Flexitron

Additionally, Transfer Tubes are different for different applicator types and should never be used on a different applicator than specified in the User Manual:

- Steel
- Titanium
- CT/MR
- Bronchial applicators
- Needles
- 4F Catheters
- 5F Catheters
- 6F Catheters

Please find the overview of correct combinations on the next page.

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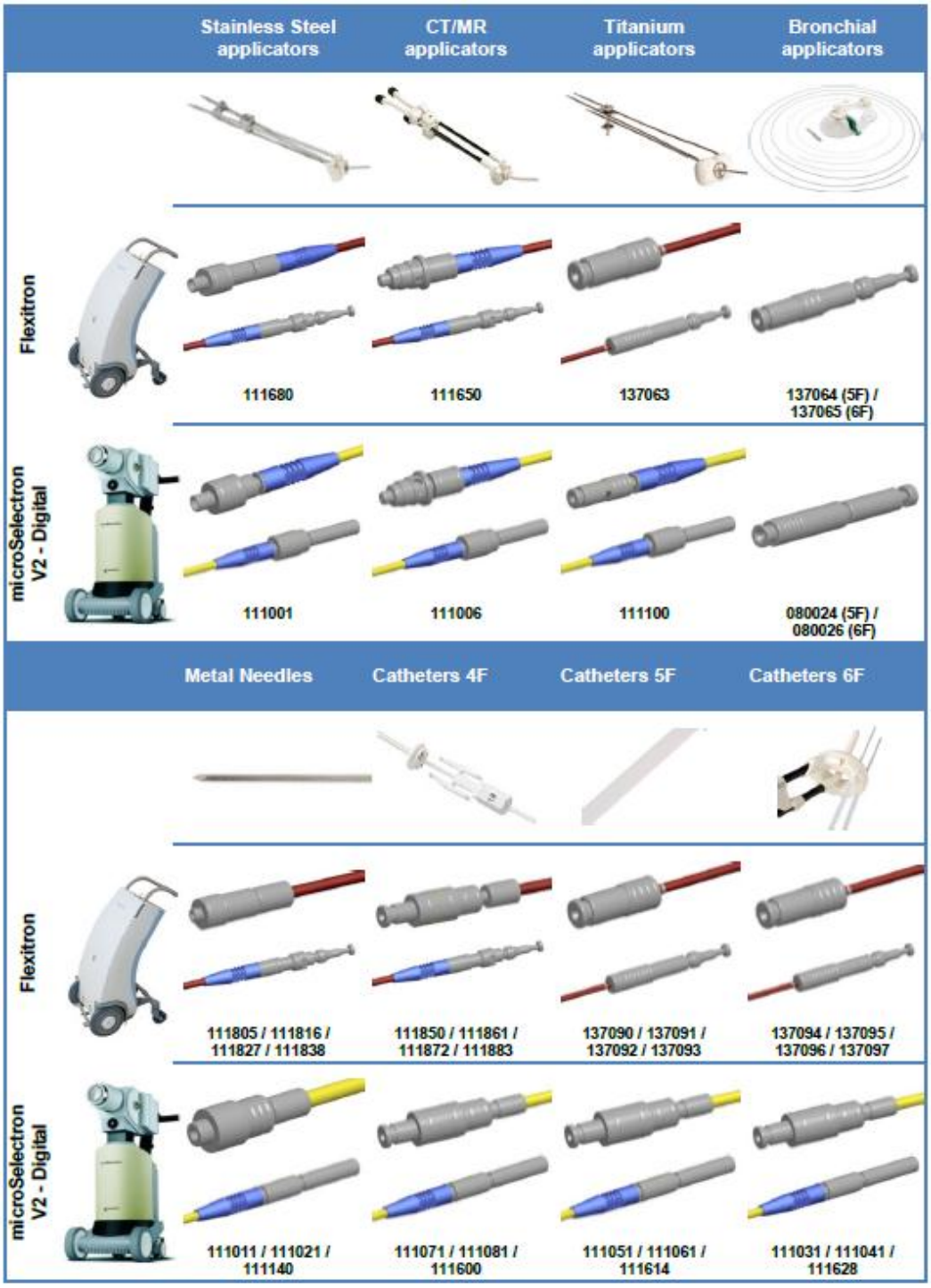

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7 Appendix: example applicator sterilization test method and results

The exemplary excerpt below is from the 84-page test report of the Vaginal CT/MR Multi Channel applicator product, part number 110.750.

The lifetime expectancy tests performed simulate 300 sterilization cycles, that in a moderate use scenario – 2 treatments per week – results in 3 years of expected life:

2 treatments/wk x 52 wk/y x 3 ≈ 300

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16. Life time requirements

#	Action or Test	Pass / Fail Criteria	Results and/or Justification or Remark	Overall Pass, TRF
1.	Evaluate the life expectancy for the reusable parts mentioned in Note 8	All mentioned parts are validated with a life expectancy of 3 years	See Note 8 and Rationale 10	☒ Pass ☐ TRF...
2.	Evaluate the shelf life of the single use parts mentioned in Note 9	All mentioned parts are validated with a shelf life of 2 years	See Note 9	☒ Pass ☐ TRF...

Note 8

Life expectancy of 3 years is validated for the mentioned parts in table 1:

Table 1	Partnumbers	Material	Rationale
# 110.752 Set of Vaginal CT/MR Multi Channel Components, 25 mm	110.753 110.754 110.755 110.772	PPSU Radel R-5100 NT15 white	Rationale 10
# 110.756 Set of Vaginal CT/MR Multi Channel Components, 30mm	110.757 110.758 110.759 110.760 110.772	PPSU Radel R-5100 NT15 white	Rationale 10
# 110.761 Set of Vaginal CT/MR Multi Channel Components, 35mm	110.762 110.763 110.764 110.765 110.772	PPSU Radel R-5100 NT15 white	Rationale 10
# 110.766 Set of Vaginal CT/MR Multi Channel Components, 40mm	110.767 110.768 110.769 110.770 110.772	PPSU Radel R-5100 NT15 white	Test 1
# 110.773 Perineal Bar Set	110.774 110.776 110.779	PPSU Radel R-5100 NT15 white	Rationale 10
# 110.778 Adapter Set for Applicator Clamp	110.784	Titanium Grade 2	Test 1
	110.779 110.783	PPSU Radel R-5100 NT15 white	Test 1
# 110.771 Set of Fixation Screws	110.772	PPSU Radel R-5100 NT15 white	Rationale 10
# 110.780 Sleeve for Titanium Intrauterine Tubes	110.781 110.782	PPSU Radel R-5100 NT15 white	Rationale 10

Validation of the life expectancy of 3 years is performed by means the following test:

Test 1

Action or Test	Pass / Fail Criteria	Results and/or	Overall

		Justification or Remark	Pass, TRF
Equipment/Materials - Set of Vaginal CT/MR Multi Channel Components, 40mm (# 110.766) - Adapter Set for Applicator Clamp (# 110.778) - Autoclave **Test** Maximum life expectancy is three years. One whole treatment procedure lasts 2-3 days (positioning, treatment, sterilization). This means maximal 2 cycles per week. 2 cycles x 52 weeks x 3 years ≈ 300 cycles. 1 autoclave sterilization cycle at 134°C lasts 3 minutes. Total sterilization time is 300 cycles x 3 minutes = 900 minutes. - Autoclave the parts of the applicator for a period of 30 minutes at 2 atm. and 134 degrees Celsius. - Repeat the autoclave test 35 times. (35 x 30 = 1050 minutes). - Check for changes of color - Check for damage or stress cracking	- A little change of color is allowed - No damage or cracking of test items	- No change of color - No damage or cracking of test items	☒ Pass ☐ TRF...
Rationale 10 Considering functionality, intended use, used materials, geometry, and the prescribed method of cleaning and sterilization as far as they influence the indicated life expectancy, the concerning parts mentioned in table 1 are similar or less worst case to the for life expectancy validated parts mentioned in test 1.			

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FCO Action Notification Report

Please complete the details below and sign the appropriate acknowledgement section:

- Existing installations; Acknowledgement by the customer
- New installations: New installation confirmation by the installing Elekta or Representative employee

Please return this report to your local Elekta Office or Representative, as soon as possible and within 30 days at the latest.

***The information in this FCO has been provided to address a safety issue and therefore the customer is expected to acknowledge and accept the recommendations given, and ensure they are implemented. By refusing to implement the recommendations, the customer assumes full responsibility and liability for all matters (including costs, losses, claims, and expenses) resulting, whether directly or indirectly from not implementing such recommendations. Further the customer will hold Elekta harmless from all matters (including costs, losses, claims and expenses) resulting, whether directly or indirectly from not implementing such recommendations.**
Failure to sign and return the acknowledgement may affect any follow-up actions necessary for us to take, and may require Elekta to report to the Regulatory Authorities in your country.

Classification:	Important User Notice	**FCO Ref:**	IUN 799701 VID: 01
FCO description:	Check Applicators and Transfer Tubes aging, integrity, cleanness and suitability		
Scope:	All users of microSelectron and Flexitron		

Hospital:	
Device Serial No: (e.g. linac - if applicable)	**Location or Site No:**

Acknowledgement by customer*:
This notification to be signed by the customer

I acknowledge that I have read and understood this FCO and accept implementation of any given recommendations:

Name: Title:

Signature: Date:

New installation confirmation:
This notification to be signed by the installing Elekta or Representative employee

Name: Title:

Signature: Date:

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